We find that, during Phase 1, a request for transmission service made after 2:00 p.m. of the day preceding the commencement of such service, will be ''made on the OASIS'' if it is made directly on the OASIS, or, if it is made by facsimile or telephone *and* promptly (within one hour) posted on the OASIS by the Transmission Provider. In all other circumstances, requests for transmission service must be made exclusively on the OASIS.

The Commission orders: The request of the How Working Group for a clarification of the OASIS Final Rule is hereby granted, as discussed in the body of this order.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 97–140 Filed 1–3–97; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Pharmaceutical, Inc. The ANADA provides for the use of a generic gentamicin sulfate intrauterine solution for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457, Fairleigh Station, St. Joseph, MO 64506–0457, is the sponsor of ANADA 200–137, which provides for the use of a generic gentamicin sulfate intrauterine solution (100 milligrams/milliliter (mg/mL)) for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

Approval of ANADA 200–137 for Phoenix Pharmaceutical's gentamicin sulfate intrauterine solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin® Solution (100 mg/mL gentamicin) in NADA 046–724. The ANADA is approved as of November 13, 1996, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended to read as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing ''000061, 000856, 000864, 054273, and 057561'' and adding in its place ''000061, 000856, 000864, 054273, 057319, and 057561''.

Dated: December 23, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–185 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 579

[Docket No. 92F–0317]

Food Additives; Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Ionizing Radiation for Treatment of Poultry Feed or Poultry Feed Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of requests for a hearing.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying the requests for a hearing on the final rule that amended the food additive regulations (animal use) to provide for the safe use of gamma radiation from cobalt-60 for rendering complete poultry feeds or poultry feed ingredients salmonella negative. Four parties filed objections to the final rule and submitted requests for a hearing requesting approval of additional energy sources for this use. After reviewing their submissions, FDA has concluded that the objections do not raise issues of material fact concerning the approval that justify granting a hearing. Therefore, FDA is denying the requests for a hearing.

DATES: The final rule published in the Federal Register of September 28, 1995, at 60 FR 50098 is effective.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of August 20, 1992 (57 FR 37825), FDA announced that a food additive petition (animal use) (FAP 2216) had been filed by Nordion International, Inc., 447 March Rd., P.O. Box 13500, Kanata, ON, Canada K2K lX8. The petition proposed that the feed irradiation regulations be amended to provide for the safe use of gamma radiation from cobalt-60, not to exceed 25 kiloGrays (kGy) (2.5 Mrad), to control salmonella in complete poultry (chickens, turkeys, ducks, geese, cornish hens, pheasant, quail, and fowl) feeds or feed ingredients. The notice of filing of FAP 2216 provided for a 60-day comment period. No comments were received.

In a final rule published in the Federal Register of September 28, 1995 (60 FR 50098), FDA amended the animal feed and pet food irradiation